DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 12, 2014

Olympus Winter & Ibe GmbH
% Mr. Graham Baillie
Gyrus ACMI Incorporated
Olympus Surgical Technologies America (OSTA)
136 Turnpike Road
Southborough, Massachusetts 01722

Re: K141225
Trade/Device Name: ESG-400
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 18, 2014
Received: July 21, 2014

Dear Mr. Baillie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141225

Device Name
ESG-400

Indications for Use *(Describe)*

The Olympus ESG-400 electrosurgical unit is intended for cutting and coagulation of tissue in open, laparoscopic and endoscopic surgery in conjunction with electrosurgical accessories and ancillary equipment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Krause -S
2014.08.12 12:42:38 -04'00'

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Electrosurgical Generator ESG-400 **Traditional 510(k) Notification**
Olympus Winter & Ibe **May 8th, 2014**

510(k) Summary of Safety and Effectiveness

General information

Applicant:	Olympus Winter & Ibe GmbH Kuehnstrasse 61 22045 Hamburg Germany
Establishment Registration No.:	9610773
Manufacturer:	Olympus Winter & Ibe GmbH Kuehnstrasse 61 22045 Hamburg Germany
510(k) Submitter:	Gyrus ACMI, Inc. Olympus surgical Technologies America (OSTA) 136 Turnpike Road Southborough, MA 01772 Phone (508) 804-2738 Fax (508) 804-2624 Establishment Registration No. 3003790304
Official Correspondent:	Graham Baillie Regulatory Affairs Manager Phone: 508.804.2738 Fax: 508.804.2624 Email: Graham.baillie@olympus-osta.com
Contact person:	Mr. Holger Nadler Phone: +49-66966-2860 Fax: +49-66966-2134 Email: holger.nadler@olympus-oste.eu
Date Prepared:	May 8th, 2014
Trade Name:	ESG-400

Device identification

Proprietary name:	ESG-400
Device Classification name:	Electrosurgical cutting and coagulation device and accessories.
Regulation Medical Specialty:	General & Plastic Surgery
Regulations Number:	21 CFR 878.4400
Regulatory class:	Class II
Product code:	GEI

Predicate device

K103032: ESG-400

Description of device

The ESG-400 is a reusable, non-sterile electrosurgical generator that features different mono- and bipolar cutting and coagulation modes. The maximum output power is 320 W. It is intended for cutting and coagulation of tissue in open, laparoscopic and endoscopic surgery in conjunction with electrosurgical accessories and ancillary equipment.
The updated ESG-400 allows Olympus Plasma Kinetic (PK) instruments to be connected at the device.

Intended use

The Olympus electrosurgical unit is intended for cutting and coagulation of tissue in open, laparoscopic and endoscopic surgery in conjunction with electrosurgical accessories and ancillary equipment.

Comparison of Technological characteristics

The ESG-400 upgrade has the identical intended use. The existing functionalities stay unaffected/unchanged and are not influenced by the modifications.
The proposed ESG-400 extends the portfolio of instruments which can be driven by the generator. Olympus plasma kinetic (PK) instruments can be connected at the existing universal socket with integrated self-recognition. To support the additional PK hand instruments, the generator's database of connectable bipolar and monopolar instruments was expanded and new output modes were implemented. Additional modes were implemented specifically for the PK instruments.

- Bipolar Coag* H
- Bipolar Coag N
- Bipolar Coag O
- Bipolar Cut** D
- Bipolar Cut F
- Bipolar Cut J
- Bipolar Cut K

*: Coagulation mode, **: Cutting mode

The range of output waveforms and power levels are identical to the FDA cleared Gyrus G400 electrosurgical generator, K081954.

Flare out detection was integrated as an additional safety feature which is available only in PK cut modes. Flare out could result from electrical current peaks during activation. The HF is immediately disabled and automatically re-activated. A warning tone is given and an error is displayed to inform the user.

User Interface (UI) modifications specifically for the additional PK instruments were amended but did not change the basic design philosophy. The GUI flow chart concept was not changed.

A monopolar cut mode (Monopolar Cut E) was added/implemented to complete the range for High Frequency (HF) instruments.

Compliance to Voluntary Standards

The design of the ESG-400 complies with the following standards:

Standard No.	Standard Title
ES60601-1:2005/A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Edition 3:2007-03	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-8:2012-11 Edition 2.1	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-2-2 Edition 5.0 2009-2	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories.
IEC 62304 First edition 2006-05	Medical device software - Software life cycle processes
IEC 62366: 2007 First edition	Medical devices - Application of usability engineering to medical devices
ISO 14971 Second edition 2007-03-01	Medical devices - Application of risk management to medical devices

Table A10-1: List of FDA recognized consensus standards

Summary of Performance Testing

The following performance testing was conducted.

1. Bench Testing
   - Bench Test Validation versus Gyrus G400
     Demonstrating the capability to use PlasmaKinetic (PK) instruments in the same manner as they are currently supported by the legally distributed/FDA cleared predicate Gyrus G400 generator, K081954.
     The same range of waveform output and power levels were used for performance and validation testing. During the validation, the waveform and test results were compared directly to the predicate device.
   - Validation with representative HF instruments.
   - Validation Comparison to Predicate Generators:

Device code	Predicate device	510(k)
I	ESG-400, Olympus Electrosurgical Generator, SW 3.06-A	K103032, K111202
II	G400 Gyrus ACMI General Surgery Workstation, SW 2.06	K081954
III	Force FX, Valleylab Electrosurgical Generator	K944602

Table A10-2: Comparison to Predicate Devices

Risk analysis was carried out in accordance with established internal acceptance criteria based on ISO-14971:2007.

Reprocessing validation was carried out in accordance with "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance – April 1996."

The software validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The device software is considered a "Minor Level of Concern."

Substantial Equivalence

Substantial equivalence is demonstrated by acknowledged verification/validation methodologies. The subject devices have identical technology, performance, dimensions and materials. The difference between the predicate and new ESG-400 is to extend the portfolio of instruments which can be driven by the generator. Olympus plasma kinetic (PK) instruments can be connected at the existing universal socket with integrated self-recognition. The proposed modifications are supported by the performance tests summarized above.

Conclusion

In summary, the upgraded ESG-400 is substantially equivalent to its predicate device.